

## **REMARKS**

The Office action mailed October 1, 2002, has been received and its contents carefully noted. The pending claims, claims 16-43, were rejected. By this amendment, claims 16, 17, 21, 22, 28-34, and 37 have been amended, claims 20, 40, and 41 have been cancelled, and claims 44-47 have been added. Support may be found in the specification and claims as originally filed. Reconsideration and entry of the amendment are respectfully requested.

### **Rejection Under 35 U.S.C. §112, first paragraph**

The Examiner rejected claim 43 under 35 U.S.C. 112, first paragraph. The Examiner deemed that "fish oil" is not described or suggested in the specification as originally filed.

Applicants respectfully submit that natural oils are referenced in the specification and that one skilled in the art notes that the most obvious source of natural oils containing EFAs is fish oil. Therefore, Applicants submit that just the mere reference of natural oils containing EFAs would reasonably convey to one skilled in the art that Applicants had possession of "fish oil" as fish oils are the most obvious source of natural oils containing EFAs. As one skilled in the art would understand that Applicants had possession of "fish oil", the rejection under 35 U.S.C. 112, first paragraph should properly be withdrawn.

The Examiner rejected claims 40-41 under 35 U.S.C. 112, first paragraph, as being nonenabled. Specifically, the Examiner deemed that the specification fails to present any evidence that the diseases and disorders listed can be treated as claimed.

Although Applicants maintain that a suitable number of diseases and disorders that represent those listed in the claims have been shown to be treatable as claimed sufficiently

enables the full scope of the claims, Applicants have cancelled claims 40-41. Applicants have added new claims 44-47.

New claims 44-47 are directed to treating a subject in need of homocysteine-lowering therapy which comprises administering the claimed formulations. The specification provides ample evidence that subjects in need of homocysteine-lowering therapy may be successfully treated with the claimed formulations. In order to determine whether a subject is in need of homocysteine-lowering therapy, one need only measure the homocysteine levels in the subject and determine if the levels are abnormally high according to conventional methods and assays known in the art. Determining whether a subject is in need of homocysteine-lowering therapy includes determining whether a subject suffers from symptoms associated with high homocysteine-levels. A variety of these symptoms are discussed in the specification and may be readily diagnosed by one skilled in the art. It is important to note that the subjects may suffer from one of the diseases or disorders listed in claims 46 and 47 and the diseases and disorders may be alleviated or treated by the therapy. However, since the claims are directed to treating a subject in need of “homocysteine-lowering therapy” and not directed to treating the listed diseases and disorders, the claimed method need not be enabled for treating the listed diseases and disorders.

As the claims directed to treating subjects in need of homocysteine-lowering therapy are enabled, the rejection under 35 U.S.C. 112, first paragraph, should properly be withdrawn.

#### **Rejection Under 35 U.S.C. §112, second paragraph**

The Examiner rejected claims 17, 20-22, 28-34, 37, and 39 under 35 U.S.C. 112, second paragraph, as being indefinite. Specifically, the Examiner pointed out the “further comprising”

and “comprises” language as well as “or the related compound” and the lack of antecedent basis in claim 16.

Applicants respectfully submit that the claims as amended obviate this rejection. Therefore, the rejection under 35 U.S.C. 112, second paragraph, should properly be withdrawn.

### **Prior Art Rejections**

The Examiner rejected claims 16-43 under 35 U.S.C. 102(b) as being anticipated, or in the alternative, under 35 U.S.C. 103(a) as obvious over EP 0 305 907, EP 0 198 804, or WO 99/03482.

Again, Applicants respectfully submit that the claims as amended are limited by the phrase “consisting essentially of”. Applicants have also deleted “linoleic acid” and “alpha-linoleic acid” from the claims. The prior art cited by the Examiner only reference linoleic acid and alpha-linoleic acid. Nowhere do the prior art teach or suggest formulations consisting essentially of at least one EFA selected from the group consisting of gamma-linolenic acid; dihomogammalinolenic acid; arachidonic acid; adrenic acid; docosapentaenoic acid; stearidonic acid; eicosatetraenoic acid (n-3); eicosapentaenoic acid; docosapentaenoic acid (n-3) and docosaheptaenoic acid, but not linoleic acid or alpha-linoleic acid, and at least one homocysteine-lowering agent. Applicants respectfully submit that the different essential fatty acids of the n-3 and the n-6 series exhibit different behaviours in the body. The characteristics of EFAs as presently claimed are not necessarily derivable from disclosures of compositions comprising linoleic and alpha-linoleic acids with vitamin B6. Therefore, one of ordinary skill in the art would not be motivated to use EFAs other than linoleic acids in combination with a homocysteine-lowering agent with a reasonable likelihood of success.

Therefore, the invention as claimed is novel and nonobvious and the rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) should properly be withdrawn.

#### **Extension of Time**

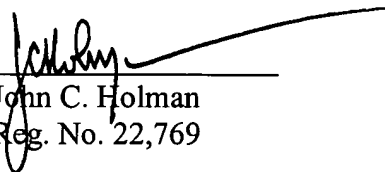
A Petition for an Extension of Time for three months under 37 C.F.R. §1.136 and the appropriate fee has been filed to extend the due date for responding to the Official Action to April 1, 2003.

#### **Conclusion**

Accordingly, in view of the foregoing amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of the claims to allow these claims and to find this application to be in allowable condition.

If the Examiner believes that a conference would be of value in expediting the prosecution of this application, the Examiner is invited to telephone the undersigned to arrange for such a conference.

Respectfully submitted,  
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